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Integration of fluoroscopy-based guidance in orthopaedic trauma surgery – A prospective cohort study

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ABSTRACT

Introduction: Computer-assisted guidance systems are not used frequently for musculoskeletal injuries unless there are potential advantages. We investigated a novel fluoroscopy-based image guidance system in orthopaedic trauma surgery.

Materials and methods: The study was a prospective, not randomised, single-centre case series at a level I trauma centre. A total of 45 patients with 46 injuries (foot 12, shoulder 10, long bones seven, hand and wrist seven, ankle seven and spine and pelvis four) were included. Different surgical procedures were examined following the basic principles of the Arbeitsgemeinschaft für Osteosynthesefragen/ Association for the Study of Internal Fixation (AO/ASIF). Main outcome measurements were the number of trials for implant placement, total surgery time, usability via user questionnaire and system failure rate.

Results: In all cases, the trajectory function was used, inserting a total of 56 guided implants. The system failed when used in pelvic and spinal injuries, resulting in a total failure rate of 6.5% ($n = 3$) of all included cases. The overall usability was rated as good, scoring 84.3%.

Conclusion: The novel image-guidance system could be integrated into the surgical workflow and was used successfully in orthopaedic trauma surgery. Expected advantages should be explored in randomised studies.

Computer-navigated systems have been used in orthopaedic surgery for nearly 20 years. Superior accuracy and reduced emission of radiation are associated with computer-aided procedures.[1–4] There are different types of navigation modalities in use. The first systems were based on preoperative computed tomography (CT) scans. Modern systems use intra-operatively acquired fluoroscopic images either in two-dimensional (2D) or, if available and most commonly used, in three-dimensional (3D) mode.[5] All these techniques depend on a reference array, which must be firmly attached to the object of interest. In most cases this is done invasively by drilling wires or screws in bones close to the target region. Exactly this dependence on a reference array limits its use in traumatology. In fracture surgery, theoretically all fragments have to be equipped with rigid markers. This could be the main reason why these systems are not used in trauma surgery on a larger scale.[6] However, despite their reported potential to reduce radiation exposure and to improve accuracy, their advantage over conventional surgery was not convincingly documented. This includes a significant learning curve, increased procedure time, intra-operative technical interference with standard workflows and lacking convincing cost–benefit analysis.[7–11]

In this pilot study, we examined a new 2D fluoroscopy-based image guidance system, which superimposes additional information (trajectory, length measurements and implant templates) on standard fluoroscopic images, provided its referencing markers are within the fluoroscopic field of view. In contrast to traditional navigation systems, the referencing device is not attached to the object of interest but is included as radio-opaque markers in different instruments such as clips or drill guides.

We intended to address three major questions with this project:

(1) Can the new system be integrated into existing surgical workflows?
(2) Does the system contribute to the treatment of patients with musculoskeletal trauma?
(3) Based on existing literature and our own experience, what are the main differences compared with existing navigation

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Table 1
Indications, surgical data, number of trials and use of the guidance system, assigned to the respective anatomical region.

Region	Indication	*n*	Implant	OR time (min)	Rad time (min)	Surgeon qualification	Trials	Tool	Modality	Main function
Foot ($n = 12$)	Fracture metatarsal V	10	Cannulated screw (Synthes) 4.5 mm	12.7 ± 5.5 (6; 23)	0.3 ± 0.14 (0.1; 0.6)	Senior assistant ($n = 5$); Consultant ($n = 4$); Head o.D. ($n = 1$);	1.6 ± 0.7 (1; 3)	1 ($n = 10$), 2 ($n = 3$)	1 all, 2 all, 3 ($n = 8$)	K-wire guidance, length
	Fracture Os cuneiforme	1	HC-screw (Synthes) ($n = 1$)	60	4.6	Consultant	1	1	1	K-wire guidance
	Fracture Os calcaneus	1	Calcaneal locking plate (Synthes)	56	0.8	Consultant	n.a.	1	1, 2	Screw length and placement
Shoulder ($n = 10$)	Acromioclavicular joint dislocation	7	Tight rope (Arthrex)	44.7 ± 14.6 (26; 65)	1.5 ± 1.9 (0.1; 5.6)	Consultant ($n = 5$); Head o.D. ($n = 2$);	1.1 ± 0.4 (1, 2)	2	1 all, 3 all	K-wire guidance
	Omarthrosis	1	Delta reverse shoulder prothesis (DePuy)	54	0.3	Head o.D.	n.a.	1	1	Trajectory to centre glenoid component
	Fracture humeral head	1	HC-screw (Synthes) ($n = 3$)	35	1	Head o.D.	1 each	1	1, 2	K-wire guidance
	Fracture of glenoid and coracoid process	1	Cannulated screw (Synthes) 3.5 ($n = 2$)	72	0.3	Consultant	1 each	1	1	K-wire guidance
Long bones ($n = 7$)	Pseudarthrosis Tibia	1	Expert nail (Synthes)	45	0.8	Head o.D.	1 each ($n = 2$)	3	1, 2	Placement of interlocking screw
	Ostelysis femur	1	LFN (Synthes)	58	4.5	Consultant	1 each ($n = 2$)	2	1, 2	Placement of interlocking screw
	Proximal femur fracture	1	Cannulated screw (Synthes) 7.3 mm	32	0.7	Senior assistant	1	1, 2, 3	1	K-wire guidance
	Distal femur fracture	1	Cannulated screw (Synthes) 7.3 mm ($n = 2$)	15	0.2	Senior assistant	1	2	1, 2	Guidewire placement and length
	Periprosthetic distal femur fracture	1	NCB plate (Synthes)	135	2.8	Consultant	n.a.	2, special tool	1, 2 and leg axis	Screw placement, leg axis
	Tibial head fracture	1	NCB plate (Synthes)	53	1.2	Head o.D.	1	2	1, 2	Screw length
	Chronic knee infection	1	Arthrodesis with Ilizarov (8 pins)	167	0.3	Senior assistant	1.1	1	1	Pin guidance
Ankle ($n = 7$)	Failed ankle arthrodesis	1	HAN (Synthes)	90	1	Head o.D.	n.a.	1	1, 2	Guidewire placement
	Primary arthodesis ankle	1	Cannulated screw (Synthes) 7.3 ($n = 3$)	56	1.1	Head o.D.	1 each	2	1, 2	Guidewire placement and length
	Pilon fracture	1	LCP, one-third tubular plate (Synthes)	120	2	Head o.D.	n.a.	1	1, 2	Plate placement, screw length
	Fracture medial malleolus	2	Cannulated screw (Synthes) 3.5 ($n = 2$)	15; 35	0.3; 1.4	Consultant	1.5 ± 1 (1; 3)	2	1, 2	K-wire guidance, length
	Trimalleolar ankle fracture	1	One-third tubular plate (Synthes), cannulated screws 3.5 mm (Synthes)	144	3.2	Senior assistant	n.a.	2	1, 2	K-wire guidance, length
	Rupture syndesmosis	1	Cannulated screw (Synthes) 4.5 ($n = 2$)	28	0.6	Assistant	1 each	2	1, 2	Screw placement and length
Hand and wrist ($n = 6$)	Scaphoid fracture	3	HC-screw (Synthes) ($n = 3$)	36.7 ± 5.7 (30; 40)	0.4 ± 0.06 (0.4; 0.5)	Hand specialist	2 ± 1 (1; 3)	1	1 all, 2 all, 3 ($n = 2$)	K-wire guidance, length
	Fracture Metacarpal I	1	K-wire 2.5	12	0.4	Hand specialist	1	1	1	K-wire placement

Table 1 (*Continued*)

Region	Indication	*n*	Implant	OR time (min)	Rad time (min)	Surgeon qualification	Trials	Tool	Modality	Main function
	Complex hand trauma and fracture distal radius	1	K-wire, LCP (Synthes)	110	3.3	Hand specialist	n.a.	1	1, 2	K-wire guidance, screw length
	Radius fracture	1	Plate (Synthes)	30	0.5	Senior assistant	n.a.	2	1, 2	Screw placement and length
Spine and pelvis (*n* = 4)	Fracture L1	1	Kyphoplastie (Kyphon)	23	1.7	Consultant	n.a.	1, 2, 3	System not applicable	System not applicable
	Pseudarthrosis Os sacrum	1	Resection, no implant	20	0.1	Head o.D.	n.a.	2	1	Define resection
	Acetabular fracture	1	Plates, screws (Synthes)	165	6.9	Consultant	n.a.	1, 2, 3	System not applicable	System not applicable
	Fracture of dens axis	1	Cannulated screws (Synthes) (*n* = 2)	28	2.6	Head o.D.	1 each	1, 2, 3	System not applicable	System not applicable

Average ± standard deviation (min; max) if applicable

n.a. = not applicable

1 = Clip (*n* = 27)
2 = Handle (*n* = 24)
3 = Sleeve (*n* = 5)

1 = Trajectory (*n* = 43)
2 = Length (*n* = 29)
3 = Bending (*n* = 17)

systems, are there any advantages and what are the limitations of the new technique?

Materials and methods

This was a prospective, not randomised, therapeutic study (level of evidence: IV – therapeutic studies, case series). All cases and indications to be included were discussed by an expert group (head: senior author of the study).

Inclusion criteria were age 18 and older, signed consent form, musculoskeletal injury and necessity for surgical treatment as well as consent from the expert group. The inclusion period was July 2009 to May 2010.

Exclusion criteria were age under 18, rejection or inability to sign the consent form, unavailability of the system or exclusion by the expert group.

A total of 46 procedures performed on 45 patients, 22 female (48%) and 23 male (52%), were included in this study (Table 1). For each procedure, the surgery was performed following the departmental standards based on principles of the Arbeitsgemeinschaft für Osteosynthesefragen/Association for the Study of Internal Fixation (AO/ASIF).

The average age was 47.4 years ± 19.8 (18; 86). All patients signed the informed consent form. The study was approved by the local and national ethics committee and monitored according to Good Clinical Practice (GCP) standards.

The guidance system (Surgix® Ver. 1.0, Surgix, Tel Aviv, Israel) was connected to the image outlet of a fluoroscope (Fig. 1). Two fluoroscopes (Arcadis Orbic 3D®, Siemens, Erlangen, Germany; Iso-C-3D®, Siemens, Erlangen, Germany) were configured to be used with the system. Consecutively each image was transferred automatically to the workstation. Whenever a surgical tool containing radio-opaque markers (Fig. 2(a)–(c)) was visible on a C-arm image, additional graphical information was superimposed on the radiographic image. For example, to precisely predict the placement of a guide- or K-wire, a clip containing radio-opaque markers was attached to the external portion of the wire (Fig. 2(c)) and the trajectory of the K-wire was displayed on the radiograph (Figs. 3(a) and (b), and 4). The system calculated and displayed the

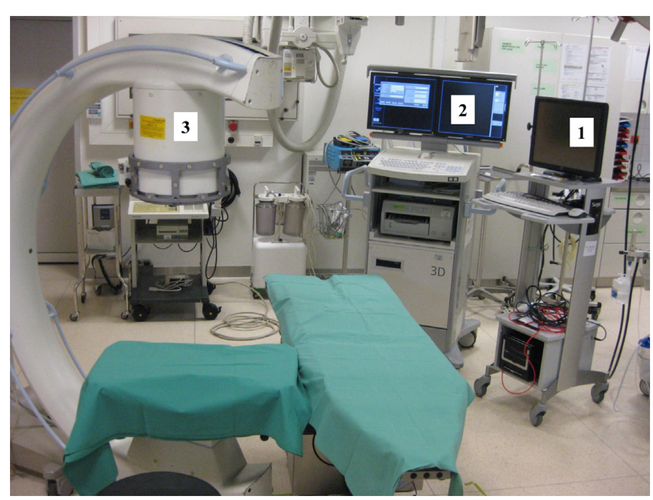

Fig. 1. The workstation (1) can be attached to the image outlet (2) of any C-arm (3). A set-up procedure is required before the system is used for the first time. Afterwards no additional referencing is required. The workstation (1) consists of a touch screen and a computer on a movable trolley. In the current version this workstation was connected to the workstation of the C-arm (2). This was done via a data cable, connected to the image outlet of the C-arm's workstation. Each image was transferred and stored automatically. In this study, two different C-arms were used. The depicted C-arm (3) is the Arcadis Orbic 3D® (Siemens®, Erlangen, Germany), which was run in pulsed 2D fluoro-mode at any time of the study.

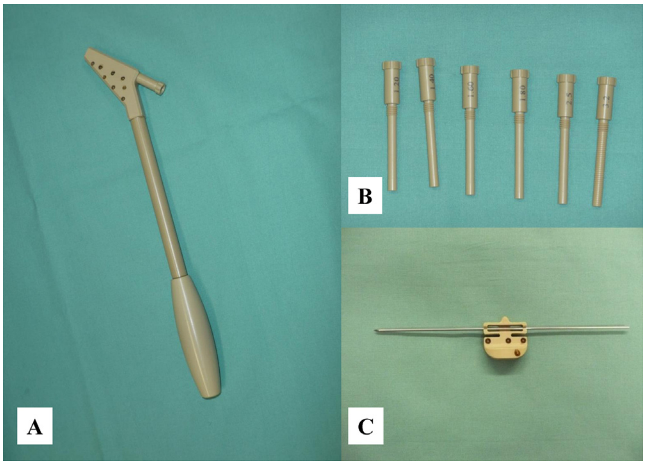

Fig. 2. Certain predefined and pre-calibrated tools contain radio-opaque markers that are detected by the system's software. They serve to automatically reference the image. Now additional information can be displayed as an additional layer in the original C-arm shot. The tools used most were a drill handle (A) with inserts with different sizes (B) and a clip (C) that can be attached to guide- or K-wires.

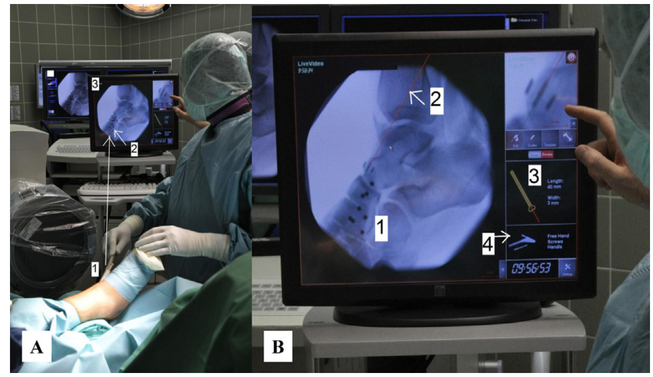

Fig. 3. (A) Intraoperative set-up with the system connected to the C-arm. The patient has a fractured medial malleolus. The tool (drill handle, 1) is in the C-arm's field of view. The image is transferred to the workstation (3). The black dots in the image (2, white arrow) are the opaque markers embedded in the tool. These markers are used to reference the image. (B) The screen of the workstation of Image 1a is enlarged. The markers are visible (1). A red line (2, white arrow) serves as a trajectory and gives the surgeon an impression of the final position of the implant. It enables the surgeon to correct the position before drilling a K-wire into the bone. Templates can simulate implants (3) and help to find the perfect size. The surgeon can switch between different tools (4) for different indications. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

accurate length of potential implants and the virtual implant template could be superimposed on the radiograph (Fig. 5(a)–(c)).

The main function is the display of a trajectory as an aiming device in the current fluoroscopic image. As the system does not use fixed reference arrays or a camera, live tracking of objects and instruments is not possible. If the position of the object or instruments is changed, that is, if the patient moves or the surgeon moves, a new image has to be obtained.

The system was run by the first author of the study in all the cases. Any system-related adverse event was recorded. In the case of a serious adverse event, the study protocol demanded an immediate exclusion and that the monitor was informed immediately.

Outcome measures were the number of trials for optimal positioning of the K-wire (if applicable), total surgery time, adverse event rate, failure rate (defined as the inability to use the system or technical defects) and radiation exposure (defined as the total duration of radiation). Following each procedure, the usability was scored via a user questionnaire (Table 2). For descriptive statistical analysis, Microsoft Excel® 2010 (Microsoft®, Redmond, WA, USA) was used.

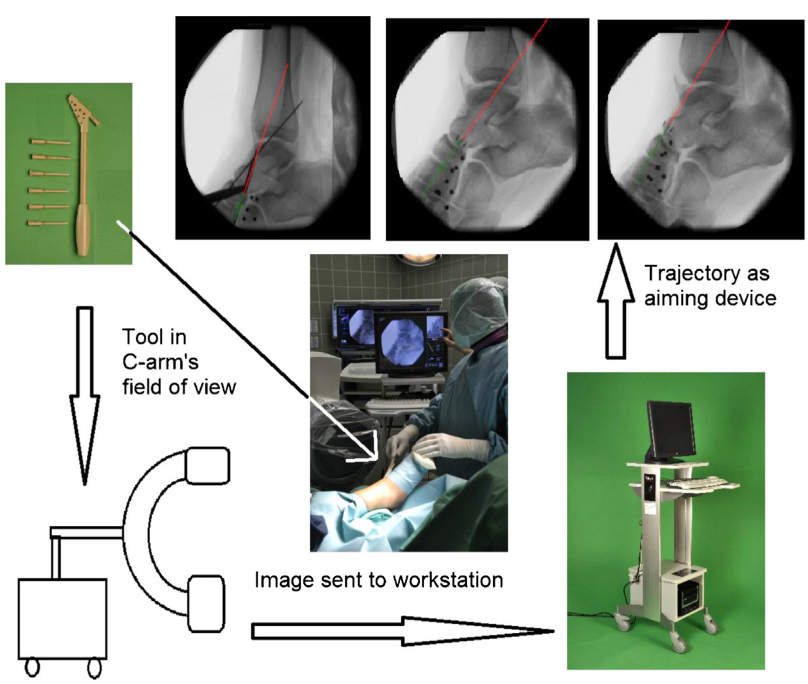

Fig. 4. Integration of the image guidance system in the surgical treatment of an ankle fracture (see Fig. 3). The guidance system is connected to a C-arm. Images are transferred automatically to the system's workstation. Whenever a referenced tool is being detected, all functions of the system can be used (i.e., trajectories, templates, length measurement, K-wire bending).

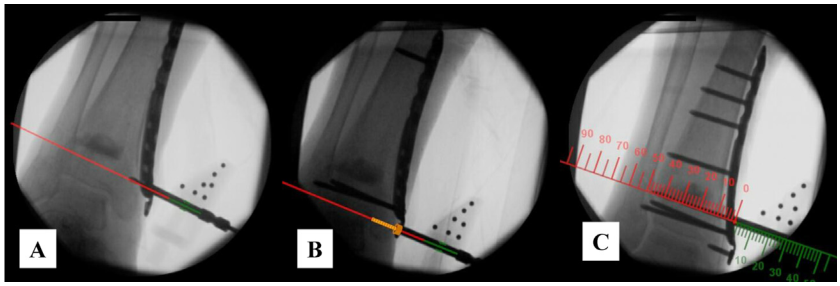

Fig. 5. (A) The trajectory was used to ensure a close and parallel position to the joint line in this case of tibia plating. (B) The template function simulates different implant sizes to assist the surgeon in choosing the right size and length. (C) Length measurements can be done on the touch screen of the workstation. This can be done by the assisting personnel and speed up the procedure by preparing all required implants in advance.

Results

The system was successfully integrated in different surgical procedures at different anatomical regions, including surgeries where traditional navigation systems are not used for various reasons (Table 1). A total of 56 implants were successfully inserted using the system's trajectory function. The average number of trials was 1.4 ± 0.8 (1; 5). In 29 cases the length-measurement tool was employed and was accurate to the millimetre in comparison to the standard measurement method.

To solve the bending problem of wires, the system analysed the position of the K-wire itself and consequently displayed a bent trajectory, presuming the final position of the wire. This function can be activated and deactivated and was mainly used in the treatment of fractures of the foot, the hand and the shoulder ($n = 19$).

The most commonly used tool was the K-wire clip ($n = 27$, 58.7%), followed by the drill handle ($n = 24$, 52.2%) and finally a drill sleeve ($n = 5$, 10.9%). Surgeons were not restricted to one tool during any one procedure.

The trajectory was the most popular feature used by surgeons ($n = 43$, 93.5%), followed by the length-measurement tool ($n = 29$, 63%) and the bending function ($n = 17$, 37%). The functions could be freely activated by the performing surgeon. In one case, an experimental tool was used to create a long-leg image by stitching single fluoroscopic images employing a special tool (Fig. 6).

Following each procedure, surgeons had to rate the general importance of a certain topic (1 = not important, 5 = very important) and the usability of the system contributing to achieve the respective aim (1 = useless, 5 = perfect assistance). The usability of the system was rated 'good' for procedures on smaller bones (hand and foot surgery, 26.4 of 32.7 points, 80.7% achieved points of general importance of each topic) and 'very good' for other indications (all other indications, 27.2 of 29.7 points, 91.6% of general importance). The overall usability was 'good', with a total of 26.9 of 31.9 points, resulting in 84.3% of the ratings of general importance (Table 2).

The system was not successfully engaged in three cases: one with a fracture of the first lumbar vertebra, one with an acetabular fracture and one with a fracture of the dens axis, resulting in a total failure rate of 6.5% ($n = 3$) of all included cases. No adverse event related to the system occurred intra-operatively.

Discussion

With this study, we intended to test the integration of a new image-based guidance system into orthopaedic trauma surgery. Furthermore, we analysed potential benefits and limitations of the new technique. In this prospective feasibility study, 45 patients with 46 various musculoskeletal injuries were included. In 43 cases, the system could be integrated into the existing surgical workflow. Surgeons having experience with navigation systems described the set-up time as minimal and the integration into the workflow as very good. The new technique was not successfully applied in surgical procedures at the spine and the pelvis.

Our study has some limitations. As impact and usability are unknown, patients were not randomised and no control group could be included and outcome parameters lack precise definition. Following this project, prospective randomised trials should investigate whether this technique is superior to current treatment pathways. An expert group decided on inclusion or exclusion, based on personal knowledge and experience, and therefore is a major bias in the study design.

Traditional computer navigation is not used in the treatment of musculoskeletal trauma on a large scale.[6,12,13] Image guidance based on 2D fluoroscopy may overcome some limitations of traditional navigation systems. Traditional navigation systems usually request a change in the accustomed surgical workflow, demand new instruments and depend on reference markers fixed to the surgical site.[6,9] Most clinical series examining navigation

Table 2
Usability outcomes.

Outcome	All		Hand and foot procedures		Other procedures	
	General importance	Achieved result	General importance	Achieved result	General importance	Achieved result
1–5; 1 = min; 5 = max						
Confidence during surgery	4.5	3.9	4.8	3.9	4.0	4.0
Handling	4.8	4.4	4.8	4.3	4.7	4.3
Time saving	4.0	3.1	4.0	2.6	3.7	3.7
Integration in workflow	4.0	3.2	4.3	3.6	3.3	2.3
Reduce radiation	4.9	3.9	4.8	3.6	5.0	4.3
Improve predictability	4.8	4.5	5.0	4.6	4.3	4.3
Improve outcome	4.9	3.9	5.0	3.8	4.7	4.3

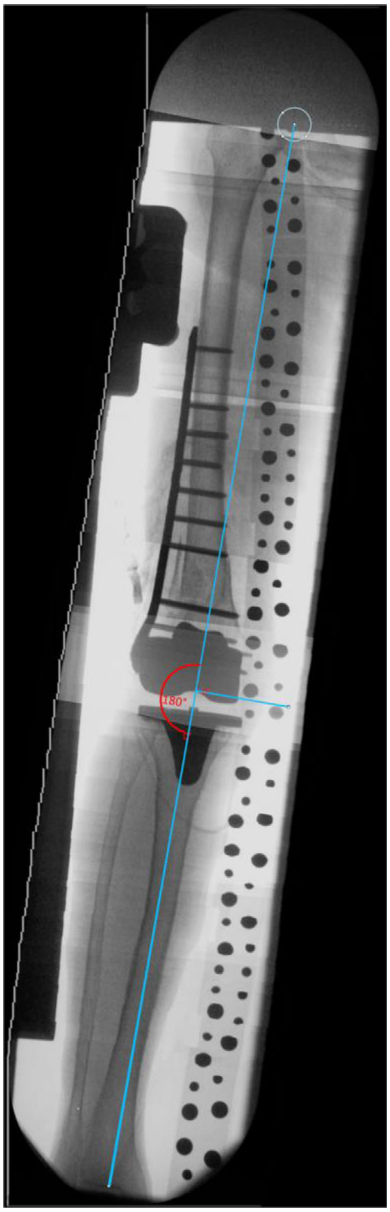

Fig. 6. A long leg X-ray was created intraoperatively on a patient with a periprosthetic distal femur fracture. The X-ray is created using multiple fluoroscopic shots. These images are stitched by the workstation. The black dots are markers inside the referenced device, which was placed underneath the patient. This can be done pre- or intraoperatively.

systems report a significantly prolonged operating room (OR) time and some show a learning curve leading initially to worse results with navigation versus conventional methods.[7,9,11]

Our new system was used by several surgeons with different training status, starting with senior assistants (from fourth year of training) to the head of department. In the ratings, the general usability of the system was good and there was no difference in the rating depending on the experience level and only a slight difference between general-trauma surgeons and hand-and-foot specialists.

The system can contribute to the treatment of patients by ensuring a very good 'first try, first hit' rate. The trajectory, displayed in the C-arm shot, improved the surgeon's confidence in the final result and was rated as 'very good', irrespective of the surgeon's experience level. The length-measurement tool was used to measure screw lengths if plating was performed and for all metatarsal fractures. These screws were chosen according to the system's template and length measurement function and checked with the surgical length-measurement tool. No implanted screw in this collective was revised intra- or postoperatively.

In one case, we tested an additional tool allowing the stitching of images, resulting in a long-leg X-ray on the OR table. In some cases with femur or tibia fractures, achieving a mechanical leg axis of 180° is challenging and remaining postoperative deformities have serious consequences for patients.[14,15] The existing methods are all very limited regarding the maximum achievable accuracy and navigated methods are reserved for specialised hospitals with the appropriate technical equipment.[16,17]

In comparison to technically highly developed, reference array-based and camera-tracked computer navigation systems, there are some major differences in the new guidance technique. The system failed to be of use for screw placement in one case with a fractured dens axis and in one case with a fractured first lumbar vertebra. It was not possible to obtain a fluoroscopic image with the referenced tool and fracture site in one C-arm shot. The same problem occurred in a case with a complex pelvic fracture. The usability of the system depends very much on the maximum field of view of the C-arm. We used standard-sized C-arms with an approximate 23-cm tube size in the pulsed fluoroscopy mode. The next C-arm generation using flat panel detectors will help in reducing this limitation significantly due to the enlarged field of view. However, the new system could not be used in classical fields of computer-assisted surgery.

On the contrary, the system was perfectly suitable for assisting in guide- or K-wire insertion in anatomical regions where traditional systems fail. The displayed trajectory assisted the surgeon in his hand–eye control and enabled him or her to correct the desired direction before inserting the wire. Most surgeons inserted the wire without acquiring images in two planes, but performed check X-rays in two planes after its insertion, thus reducing the problem of a missing second plane.

However, not only wire insertions can benefit from the system. The aiming (trajectory) tool was described as very helpful to reach a screw position close and parallel to the joint line without penetrating the cartilage (i.e., pilon fracture). Furthermore, we used the system to insert locking screws ($n = 4$) for intramedullary nailing. The system's ability to display trajectories was helpful, but, particularly for this indication, the missing second plane limits the usability. It was simply not possible to keep the position of the first plane until the required second plane was obtained. For this indication, we usually use a radiolucent drive with angular gear and this is still the method of choice after this feasibility study.

For the same indication, other methods employing image-based and image-free modalities have been described as helpful, but no method was really accepted as a new standard.[18,19] In radiological interventions, trajectory-based aiming tasks are meanwhile standard and routine procedures for some indications, but not for musculoskeletal conditions. Usually these procedures use magnetic resonance imaging (MRI) or CT scans and are mainly used for biopsies or guidewire guidance. The accuracy is described as better than with conventional fluoroscopy-assisted methods.[20,21] There are no reports on using such techniques in general traumatology. Of course, only a few special theatres offer such imaging modalities, and most operating rooms equipped with CT or MRI are run by neurosurgeons in tumour surgery.[22]

A major limitation to the widespread use of reference-based navigation systems are the high costs of acquisition and maintenance. An accurate cost–benefit analysis is not possible at this moment because our system is a prototype and not commercially available. We expect the costs to be much lower, particularly if the software can be integrated in an existing C-arm.

In summary, the simple design and the good integration in the accommodated workflow allow this system to be used in many musculoskeletal procedures. Besides displaying a trajectory, the clinically most important function is the stitching of C-arm images to create long-leg X-rays intra-operatively. This function should be further developed and examined in clinical series, as it addresses an unsolved or at least unsatisfactorily solved problem. We see the system as an optimal amendment to traditional navigation systems, not as a substitute. Our first encouraging results now have to be confirmed in randomised, prospective projects. Finally, no navigated technique was able to show a long-term benefit in patient-related outcome parameters. However, particularly this proof could convince a larger group of surgeons to accept new technologies in their daily work.

Conclusion

This pilot study validated the clinical application of a fluoroscopy-based image-guidance system for various musculoskeletal injuries. Its major advantage is the high integrability into the accustomed surgical workflow and its connectivity with existing technical equipment. It can hardly be compared to known navigation solutions, as instruments are not tracked and fixed reference arrays are not required. It was very usable for all guide- or K-wire-based indications but was limited in other surgical fields such as spinal or pelvic surgery. The ability is very promising to stitch single images and create long-leg X-rays on the OR table, to achieve a straight axis following fracture treatment on the femur and tibia. The ultimate requirement for assistance in fracture reduction has still not been reached and no technical solution overcomes the technical limitations in solving the problem of guiding multiple fragments under permanent control, but we present a usable technical extension of existing intra-operative imaging modalities to potentially improve surgical-outcome parameters. In particular, the long-leg X-ray function should be further developed and examined in prospective clinical series.

Conflicts of interest

The authors declare that there is no conflict of interest.

Source of funding

Technical support was provided by Surgix (Surgix®, Tel Aviv, Israel) in delivering and maintaining the guidance system and Siemens (Siemens®, Erlangen, Germany) in connecting the guidance system to the fluoroscopes.

No company had influence in the collection of data or contributed to or had influence on the conception, design, analysis and writing of the study. No further funding was received.

No author is affiliated to any of the supporting companies or received or will receive any form of payment related to this study.

Ethical approval

The study was approved by the local (Ethikkomission Universität Ulm, Nr. 159, 09) and the international (freiburger ethickommission, Nr. 09/1385) Ethics Committee and has been performed in accordance with the ethical standards in the 1964 Declaration of Helsinki.

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